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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,904	09/30/2003	Cecil Kost	MMSI121562	8999
26389	7590 08/01/2005		EXAM	INER
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC			LASTRA, DANIEL	
SUITE 2800	IFTH AVENUE 2800		ART UNIT	PAPER NUMBER
SEATTLE,	WA 98101-2347		3622	
	•		DATE MAILED: 08/01/200:	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Comment	10/674,904	KOST ET AL.				
Office Action Summary	Examiner	Art Unit				
	DANIEL LASTRA	3622				
The MAILING DATE of this communication a Period for Reply	appears on the cover sheet with the	ne correspondence address				
A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a - If NO period for reply is specified above, the maximum statutory peri - Failure to reply within the set or extended period for reply will, by start Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may a reply be reply within the statutory minimum of thirty (30) od will apply and will expire SIX (6) MONTHS tute, cause the application to become ABAND	be timely filed days will be considered timely. from the mailing date of this communication. DNED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 09	June 2005	·				
	his action is non-final.					
3) Since this application is in condition for allow	,—					
Disposition of Claims						
4) ☐ Claim(s) 1-10,16-25,31-45 and 51-55 is/are 4a) Of the above claim(s) is/are withd 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-10,16-25,31-45 and 51-55 is/are 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and	Irawn from consideration.					
Application Papers						
9)☐ The specification is objected to by the Exam	iner.					
10)☐ The drawing(s) filed on is/are: a)☐ a	· · · · · · · · · · · · · · · · · · ·					
Applicant may not request that any objection to t		·				
Replacement drawing sheet(s) including the corr		•				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for forei a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the p application from the International Bure * See the attached detailed Office action for a l	ents have been received. ents have been received in Application of the contract of the contrac	cation No eived in this National Stage				
Attachment(s)	•					
1) Notice of References Cited (PTO-892)	4) Interview Summ					
 Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date 	Paper No(s)/Ma 5) Notice of Inform 6) Other:	al Patent Application (PTO-152)				

Art Unit: 3622

DETAILED ACTION

1. Claims 1-10, 16-25, 31-45 and 51-55 have been examined. Application 10/674,904 has a filing date 09/30/2003 and Claims Priority from Provisional Application 60/472,956 (05/22/2003).

Response to Amendment

2. In response to Non-Final Rejection filed 05/23/2005, the Applicant filed an Amendment on 06/09/2005, which amended claim 1. Applicant's amendment did not overcome the Section 101 rejection.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of: (1) whether the invention is within the technological arts; and (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory

Art Unit: 3622

subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, the instant claims fail to recite the use of any type of technology (e.g. computer system) within the recited steps of a system for promoting pharmaceutical drugs.

Mere intended or nominal use of a component, albeit within the technological arts, does not confer statutory subject matter to an otherwise abstract idea if the component does not apply, involve, use, or advance the underlying process.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result.

Although the claimed invention produces a useful, concrete and tangible result, since the claimed invention as a whole is not within the technological arts, as explained above, claims 1-3 and 5 are deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 16-25, 31-45 and 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Feeney (US 2002/0032582).

As per claim 1, Feeney teaches:

Art Unit: 3622

A computer-implemented system for promoting pharmaceutical drugs, comprising:

a set of brand rules for guiding a distribution of drug samples of a drug (see paragraphs 14, 37; 274-275); and

a drug sample fulfillment platform for implementing the set of brand rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative (see paragraphs 40, 59-61, 118, 216, 239, 241, 257-260, 268, 282-284).

As per claim 2, Feeney teaches:

The system of Claim 1, wherein drug samples include physical samples (see paragraph 246).

As per claim 3, Feeney teaches:

The system of Claim 1, wherein drug samples include a pad of pre-printed vouchers (see paragraph 118).

As per claim 4, Feeney teaches:

The system of Claim 1, wherein drug samples include a coupon printed in the office of the prescriber, which is networked to the drug sample fulfillment platform (see paragraph 282).

As per claim 5, Feeney teaches:

The system of Claim 1, wherein the drug samples, which are in a printed form, are redeemable at a pharmacy, redeemed data being generated by the drug sample fulfillment platform for refining the brand rules so as to better guide distribution of the drug samples (see paragraph 282-284).

Art Unit: 3622

As per claim 6, Feeney teaches:

A system for distributing pharmaceutical drugs, comprising:

a drug sample fulfillment platform for accessing drug sample services (see paragraphs 258, 273); and

a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples (see paragraphs 258, 273).

As per claim 7, Feeney teaches:

The system of Claim 6, further comprising a second set of Web pages coupled to the drug sample fulfillment platform through which a sales representative can access the drug sample fulfillment platform to print coupons (see paragraph 284).

As per claim 8, Feeney teaches:

The system of Claim 6, further comprising a third set of Web pages coupled to the drug sample fulfillment platform through which a patient can access the drug sample fulfillment platform to obtain sample vouchers (see paragraph 118).

As per claim 9, Feeney teaches:

The system of Claim 6, wherein the first set of Web pages display a list of drug samples available to the prescriber to order drug samples in a form selected from a group consisting of physical samples, pre-printed vouchers, and print on-demand coupons (see paragraph 275, 284-285).

As per claim 10, Feeney teaches:

Art Unit: 3622

The system of Claim 6, wherein the first set of Web pages display a list of the order history of the prescriber, the list including a date and a drug sample ordered by the prescriber (see paragraphs 216, 290).

As per claim 16, Feeney teaches:

A drug sample fulfillment platform, comprising:

a drug sample Web site for mating with a portal that is selected from a group consisting of prescriber-oriented Web portals, an e-Detailing service, a Web site regarding a drug brand, and an online physician learning site (see paragraph 290); and

a request database for receiving requests of a prescriber through the drug sample Web site for drug samples, the request database responding to the prescriber by allowing the prescriber to print coupons or to print an order form for physical samples or pads of pre-printed vouchers (see paragraphs 284, 118, 258-260).

As per claim 17, Feeney teaches:

The drug sample fulfillment platform of Claim 16, wherein the request database receives claim information when a patient redeems a print coupon or a preprinted voucher for physical samples (see paragraph 52).

As per claim 18, Feeney teaches:

The drug sample fulfillment platform of Claim 17, wherein the request database produces a first report accounting for the number of coupons or vouchers redeemed by patients of the prescriber (see paragraphs 274-275)

As per claim 19, Feeney teaches:

Art Unit: 3622

The drug sample fulfillment platform of Claim 18, wherein the request database produces a second report correlating an allocation of drug samples of a drug to the prescriber with the number of prescriptions written by the prescriber relating to the drug (see paragraph 275).

As per claim 20, Feeney teaches:

The drug sample fulfillment platform of Claim 19, wherein the request database produces a third report accounting for the monetary amount spent by a pharmaceutical company on a drug sample fulfillment program for a drug and a monetary amount associated with prescriptions written by the prescriber for the drug (see paragraphs 274-275).

As per claim 21, Feeney teaches:

A networked system for ordering pharmaceutical sample drugs, comprising:

a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink, the drug sample Web site presenting a Web page including selectable options for the prescriber to order drug samples (see paragraph 258-259, 284-285).

As per claim 22, Feeney teaches:

The networked system of Claim 21, wherein the drug samples are in a form selected from a group consisting of physical samples and pre-printed vouchers (see paragraphs 118 and 159).

As per claim 23, Feeney teaches:

Art Unit: 3622

The networked system of Claim 21, wherein the selectable options of the Web page include a quantity for each drug sample, which is specifiable by the prescriber (see paragraph 259).

As per claim 24, Feeney teaches:

The networked system of Claim 21, the selectable options of the Web page include a delivery location to which the drug samples will be shipped (see paragraph 111).

As per claim 25, Feeney teaches:

The networked system of Claim 21, wherein the selectable options of the Web page include an option for printing on-demand vouchers on a printer in the office of the prescriber (see paragraph 284).

As per claim 31, Feeney teaches:

A method for accessing a drug sample fulfillment platform, comprising:

activating a link to access the drug sample fulfillment platform from a Web portal (see paragraph 195); creating a transaction that includes a prescriber identifier and a partner identifier; and

mating a drug sample Web site to the Web portal allowing a prescriber to navigate and order drug samples (see paragraphs 258-259; 284).

As per claim 32, Feeney teaches:

The method of Claim 31, further comprising formatting a set of Web pages of the drug sample Web site prior to the act of mating to emulate the look and feel of the Web portal (see paragraph 284).

Art Unit: 3622

As per claim 33, Feeney teaches:

The method of Claim 31, causing the prescriber to register if the prescriber identifier is not found in a request database (see paragraph 189).

As per claim 34, Feeney teaches:

The method of Claim 31, based on a segment to which the prescriber belongs, determining one or more of the following:

what drug samples that are available to the prescriber (see paragraphs 258-259; 284);

a drug sample quantity limit that is available to the prescriber (see paragraph 259);

a drug sample time limit in which the drug sample quantity limit is available (see paragraph 259); and the type of sample that is available to the prescriber (see paragraphs 258-259).

As per claim 35, Feeney teaches:

The method of Claim 34, receiving a selection for physical samples, the act of receiving including receiving a drug selection, a type of drug sample selection, a quantity of drug sample selection, and a delivery address (see paragraphs 258-259; 111).

As per claim 36, Feeney teaches:

The method of Claim 35, receiving a print request to print an order form capturing the drug selection, the type of drug sample selection, the quantity of drug sample selection, and the delivery address (see paragraph 219, 111).

Art Unit: 3622

As per claim 37, Feeney teaches:

The method of Claim 36, recording the requesting activities of the prescriber in a request database (see paragraph 275).

As per claim 38, Feeney teaches:

The method of Claim 34, receiving a selection for pre-printed vouchers or print coupons, the act of receiving including receiving a drug selection, and a quantity of coupons to be printed (see paragraphs 284-285).

As per claim 39, Feeney teaches:

The method of Claim 38, receiving a ship request to ship the pre-printed vouchers or a print request to print coupons capturing the drug selection (see paragraphs 118, 111, 284).

As per claim 40, Feeney teaches:

The method of Claim 39, recording the requesting activities of the prescriber in a request database (see paragraph 275).

As per claim 41, Feeney teaches:

The method of Claim 40, receiving a request to print a first report that lists registration data of the prescriber, the requesting activities of the prescriber, and the claim data from a claim processor that is indicative of redeemed pre-printed vouchers and print coupons at pharmacies (see paragraphs 274-275).

As per claim 42, Feeney teaches:

Art Unit: 3622

The method of Claim 40, receiving a request to print a second report that correlates drug samples of a drug distributed to the prescriber and with prescriptions written by the prescriber relating to the drug (see paragraphs 274-275).

As per claim 43, Feeney teaches:

The method of Claim 40, receiving a request to print a third report that accounts for the return on investment for a monetary amount spent on a drug sample distribution program for a drug and the monetary amount received from prescriptions for the drug (see paragraphs 274-275).

As per claim 44, Feeney teaches:

The method of Claim 40, detecting fraud by comparing the drug sample quantity limit and the time frame in which the drug sample quantity limit is available to the prescriber and the claim data which is indicative of the number of pre-printed vouchers and print coupons redeemed by patients (see paragraphs 284-285)

As per claim 45, Feeney teaches:

The method of Claim 40, refining the drug sample quantity limit of the prescriber based on the number of redemptions of pre-printed vouchers and print coupons associated with the prescriber (see paragraph 282).

As per claim-51, Feeney teaches:

The system of Claim 1, wherein said fulfillment platform comprising:

A pharma rules sample engines for performing personalization and intelligent brand rule implementation (see paragraphs 37, 274-275);

Art Unit: 3622

A marketing sample engine for integrating with drug samples suppliers and Web portals for prescribers (see paragraphs 281-282) and

The pharma rules sample engine and the marketing sample engine being based on the set of brand rules and on a set of prescriber preferences (see paragraph 258-259).

As per claim 52, Feeney teaches:

The system according of claim 51, wherein the marketing sample engine links the drug sample fulfillment platform to one or more suppliers and drug samples so as to inhibit the lack of supply of sample drugs desired by the prescriber or inhibit the inconsistent supply of drug samples desired by the prescriber (see paragraph 259).

As per claim 53, Feeney teaches:

The system according to claim 6, wherein said fulfillment platform implementing a set of brand rules under which pharmaceutical drug samples are distributed, wherein said brand rules include: product; allocation quantity; sample type selected from a group consisting of live samples, pre-printed samples and on-demand samples; and, drug strength (see paragraph 275).

As per claim 54, Feeney teaches:

The system according to claim 6, wherein said fulfillment platform implementing a set of brand rules for distributing pharmaceutical drug samples, said brand rules including timing considerations that are selected from a group consisting of sample offer time limits and rolling expiration dates for vouchers from either within or between brands for which a quantity of drug samples can be ordered (see paragraph 275).

As per claim 55, Feeney teaches:

The system according to Claim 6, wherein said fulfillment platform comprising a pharma rules sample engine for implementation brand rules under which a prescriber may obtain drug samples, the pharma rules sample engine modifying the brand rules so as to change a quantity limit of drug samples to be distributed to the prescriber (see paragraph 282).

Response to Arguments

5. Applicant's arguments filed 06/09/2005 have been fully considered but they are not persuasive. Claims 1-3 and 5 are deemed to be directed to non-statutory subject matter because a machine/computer is not being used to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative.

The Applicant argues that the Feeney system is based on its ability to control dispensers and if Feeney cannot control the dispensers, nothing will work in the system of Feeney. The Examiner answers that the Applicant is arguing about features that are not stated in the claims.

The Applicant argues that Feeney does not teach "a drug sample fulfillment platform for implementing the set of brand rules to allow prescriber to obtain drug samples to dispense to a patient without the use of a sales representative". The Examiner answers that Applicant discloses in page 7 of Applicant's specification "After the brand manager 204 has selected a group of prescribers 210, the brand manager 204 produces a set of brand rules 206 which define the availability of drug samples to each of the prescribers 210". The set of brand rules 206 may cause one prescriber's

drug sample availability and characteristics to be different from those of another prescriber". Feeney teaches in paragraphs 59-61 "[0059] The present system also can collect, process and make available to pharmaceutical companies, via a remote web browser, or an email accurate and up-to-the-minute data regarding the sample medication dispensing practices of individual physicians, results of detailing efforts and current medical office sample inventory. This method of data collection, processing and presentation greatly increases the work efficiency of pharmaceutical representatives and provides pharmaceutical companies with information that was rarely obtainable previously. The present system provides the medical office with a data stream by which sources, such as pharmaceutical companies and other interested entities, can target product promotions to patients of specific physicians by transmitting electronic coupons to the point of dispensing. Additionally, the present system provides a mechanism by which drug and other companies can present specifically targeted product and educational information to interested physicians and office staff. Using the data collected from the sampling programs and prescription dispensing programs, the system can target product information to only interested physicians". Therefore, Feeney teaches a system that defines a set of brand rules based upon sample medication dispensing practices of individual physicians, results of detailing efforts and current medical office sample inventory to target product promotions (i.e. physical samples, coupons or vouchers for samples medications) to said individual physicians. Each individual physician would be targeted with different samples medications promotions

based upon said physician sample medication dispensing practices and sample inventory levels, similar to the Applicant's claimed invention.

Page 15

The Applicant argues that Feeney does not teach "a drug sample fulfillment platform for implementing the set of brand rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative". The Examiner answers that Feeney teaches in paragraph 268 "As with all of the other subsystems, such as, the OTC subsystem, the prescription subsystem, and the sample management subsystem, the patient care item subsystem can capture inventory levels and provides automated re-ordering functionality along with reports to track dispensing practices and trends". Also, Feeney teaches "An aspect of the present system relates to a system for integrating data management with the process of controllably dispensing products at the point of care. The system can include a patient information database configured to maintain patient information and one or more dispensers configured to controllably dispense a product in response to a control signal from a prescription module. The system also can include a prescription module to receive a prescription for the product and to initiate an adjudication check for the product utilizing the patient information. The prescription module further can transmit the control signal to the one or more dispensers to release the product. The system further can include an inventory management module to control and manage the inventory of the product. The inventory management module can be configured to control and manage a physical inventory and a virtual inventory for the product. The inventory management module can be configured to manage and control the virtual inventory by

tracking ownership and utilization of a plurality of individually owned and co-mingled product inventories in the one or more dispensers. Access to a product in inventory further can be controlled according to ownership of the product as tracked in the virtual inventory. Also, the inventory management module can be configured to manage and control a physical inventory by sending a reorder message to reorder a product when an inventory level is at a predefined level. The predefined level can include a par inventory level. The predefined level can include a dynamic par level that is based upon medical office product usage, for example. The system further can include a central server connected via a network to the inventory management module. The central server can be connected to an ERP subsystem that is configured to receive and process the reorder message" (see paragraph 40). Paragraph 255 teaches "One method is the semi-auto reorder method in which the physician can initiate the process when inventory is low or in order to obtain a new medication, for example". Also, Feeney teaches in paragraph 258 "Fig 15 is a task flow of the process for selecting new medications to add to inventory. The subsystem displays a list of medications that are available for addition to inventory... If the medication is on formulary, the subsystem then prompts for selection of the medication and for selection of the requesting physician". Therefore, Feeney teaches a sample management subsystem that monitors sample medication dispensing practices of individual physicians, results of detailing efforts and current medical office sample inventory (i.e. brand rules) for the purpose of restocking the physician sample inventory using an ERP subsystem and without the use

of a sales representative to accomplish said restocking, similar to Applicant's claimed invention.

Page 17

The Applicant argues that nothing in Feeney paragraph 284 teaches "a drug sample fulfillment platform for implementing the set of brand rules to allow a prescriber to obtain a drug samples to dispense to a patient without the use of a sales representative". The Applicant argues that in his claimed invention the prescriber can access the drug sample fulfillment platform that implements the set of brand rules to obtain drug samples without waiting just prior to each approval to dispense a medication. The Applicant further argues that for example, pre-printed vouchers are available to the prescriber in Applicant's claimed invention without the need for a front office server to communicate to the central server to determine an eCoupons for retrieval. The Examiner answers that the reason Feeney discloses in paragraph 284 "prior to each approval to dispense a medication" is because sample medications are prescriptions products that need prior approval from a license physician before dispensing said samples to a patient. Said prior approval is obtained from a physician by said physician signing a prescription (i.e. voucher or a coupon) for said sample medication. Furthermore, Applicant is arguing about features that are not in stated in the claims. Claim 9 recites "The system of Claim 6, wherein the first set of Web pages display a list of drug samples available to the prescriber to order drug samples in a form selected from a group consisting of physical samples, pre-printed vouchers, and print on-demand coupons". Therefore, in the Applicant's claimed invention a prescriber has to communicate with a web server which would display the Webpages to said

prescriber's computer, so said prescriber is able to order pre-printed vouchers, electronic coupons or print coupons using said prescriber's computer terminal, similar to the Feeney invention.

The Applicant argues that there is nothing in Feeney that teaches the ability of a prescriber to access the drug sample fulfillment platform to order drug samples through a first Web pages. The Examiner answers that Feeney teaches in paragraph 319 that the communication between a server 12 in the medical office 10, the pharmacy adjudication subsystem 32 and the ERP subsystem (e.g. handles the ordering process; see paragraph 29) can be provided through a secure Internet connection and paragraph 282-284 teaches the delivering and printing of e-coupons via the Internet to the physician medical office. Therefore, Feeney teaches a drug sample fulfillment platform to order drug samples through webpages, similar to Applicant's claimed invention.

The Applicant argue that Feeney does not teach "allowing a prescriber to print coupons or to print an order form for physical samples or pads of preprinted vouchers" because in Feeney in paragraph 284 a hardcopy of the e-coupon can be provided only just prior to each approval to dispense a medication. The Examiner answers with the same argument made above regarding paragraph 284.

The Applicant argues that there is nothing in Feeney about pads of pre-printed vouchers. The Examiner answers that it is inherent that if Feeney's physicians are targeted with vouchers and coupons which can be printed by in hard copy form (see paragraph 282-284; 118), then Feeney's physician would receive a pads of pre-printed vouchers to allow patients to have their sample filled at another location.

The Applicant argues that there is nothing in Feeney of mating a drug sample Web site to the Web portal allowing a prescriber to navigate and order drug samples. The Examiner answers that Feeney teaches in paragraphs 282-284 a system that delivers coupons for sample medication to physicians via the Internet and where said physicians connect to a central server website to select and print said coupons. Therefore, Feeney teaches a webportal that allows prescribers to navigate and order drug samples, similar to Applicant's claimed invention.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL LASTRA whose telephone number is 571-272-6720. The examiner can normally be reached on 9:30-6:00.

Art Unit: 3622

Page 20

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ERIC W. STAMBER can be reached on 571-272-6724. The Examiner's Right fax number is 571-273-6720.

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Daniel Lastra July 14, 2005

RETTAYEL ER